MAY - 2 2001

K002334

ADMINISTRATIVE INFORMATION

Manufacturer Name:
MacroPore, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact:
Kenneth K. Kleinhenz
Director of Regulatory Affairs
Telephone (858) 458-0900
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DEVICE NAME

Classification Name: Plate, Cranioplasty, Non-Alterable

Trade/Proprietary Name: MacroPore*NS* CraniLoc

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 882.5330 Non-Alterable Cranioplasty Plates are intended for use in craniotomy procedures and are classified as Class II. Non-Alterable Cranioplasty Plates have been assigned Product Code GXN.

INTENDED USE

MacroPore*NS* CraniLoc is indicated for the fixation of bone flaps after a craniotomy.

DEVICE DESCRIPTION

Design Characteristics

MacroPore*NS* CraniLoc is a resorbable, macroporous implant manufactured from polylactic acid (PLA). The MacroPore*NS* CraniLoc is composed of a threaded male and tapped female disk that screw into each other. The MacroPore*NS* CraniLoc utilizes two mating disks that incrementally engage each other via a threaded shaft, resulting in a compression force that stabilizes adjacent bone fragments without the need for external fixators (screws, tacks, etc.). The MacroPore*NS* CraniLoc is designed to fit into an drilled hole or osteotomy cut and exert vertical pressure to stabilize flap movement in both the vertical and horizontal directions. Typically, 3 or more MacroPore*NS* CraniLocs will be used to secure a bone flap. Once engaged to the desired compression force, the shaft of the MacroPore*NS* CraniLoc can be cut to make the shaft flush with the anatomy. Various manual instruments (drivers, excision devices, etc.) are used in conjunction with the MacroPore*NS* CraniLoc to assist in the installation process.

The MacroPore*NS* CraniLoc comes in two basic designs, one for use in burr holes and another style for use in the osteotomy cut. The design features between the burr hole version and the osteotomy line version are virtually identical except that the burr hole models have a round stem while the osteotomy line models have a semi-round stem with two flattened sides. The MacroPore*NS* CraniLoc is provided in various sizes to fit burr holes ranging from 8mm to 19mm in diameter. The MacroPore*NS* CraniLoc is also designed to fit into the osteotomy line where 1-2mm of clearance is available. The pore size of the upper and lower disks ranges from 500 microns to 3000 microns in diameter, with pores distributed uniformly throughout. The thickness of the MacroPore*NS* CraniLoc's disks ranges from 0.50 mm to 2.0 mm according to the anatomical region to be treated. The outer diameter of the MacroPore*NS* CraniLoc shaft ranges from 1mm to 10mm. The shaft of the MacroPore*NS* CraniLoc's male component may be provided as either solid or cannulated, depending on strength requirements. The larger shaft diameters may also be porous with holes to allow for in growth of bone and tissues.

Material Composition

The MacroPore*NS* CraniLok is fabricated from polylactic acid (PLA).

In Vitro Testing

Mechanical testing of the MacroPore*NS* CraniLok demonstrates that the device is substantially equivalent to the predicate. Test results indicate that the mechanical properties of the MacroPore*NS* CraniLok are substantially equivalent to the mechanical properties of the predicate device under indication for use conditions.

EQUIVALENCE TO MARKETED PRODUCT

The MacroPore*NS* CraniLoc shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: Aesculap CranioFIX Titanium Clamp System and Walter Lorenz RapidFlap Cranial Clamp, Class II medical device that were cleared for marketing in the United States under K972332 and K991029 respectively.

The MacroPore*NS* CraniLoc is composed of the same raw material and processed in the same manner as previously FDA cleared medical devices from MacroPore

- K983360 MacroPore Protective Sheet
- K972913 MacroPore (Protego System) plates, screws, and Protective Sheet
- K000992 MacroPore*DX* Distractor
- K994158 MacroPore*OS* Protective Sheet

Indications For Use

The MacroPore*NS* CraniLoc and the predicate device share substantially equivalent indications for use as they both are indicated for the fixation of bone flaps after a craniotomy. Specifically, the MacroPore*NS* CraniLoc is indicated for the fixation of bone flaps after a craniotomy.

Design and Materials

The MacroPore*NS* and the predicate device share substantially equivalent design features as both devices are composed of two disks that are attached through a threaded stem. Both devices secure bone in an identical manner as both the MacroPore*NS* CraniLoc and the predicate device press the bone cover and the vault of the cranium between two disks. Both the MacroPore*NS* CraniLoc and the predicate device utilize two mating disks that incrementally engage each other via a threaded shaft, resulting in a compression force that stabilizes adjacent bone fragments without the need for external fixtures (screws, tacks, etc.). The MacroPore*NS* CraniLoc and the predicate also share design characteristics of fitting into a drilled burr hole or fitting into the osteotomy cut. Both the MacroPoreNS CraniLoc and the predicate share principles of operation as they both exert vertical pressure to stabilize flap movement in both the vertical and horizontal directions. Both the MacroPore*NS* CraniLoc and the predicate utilize various manual instruments (drivers, excision devices, etc.) to assist in the installation process.

SUMMARY : TABLE OF SUBSTANTIAL EQUIVALENCE

The MacroPore*NS* CraniLoc is substantially equivalent to the Aesculap CranioFIX and the Walter Lorenz RapidFlap devices in the following respects:

	Subject Device	**Predicate Device**		**Related Device**		
	MacroPore MacroPore*NS* CraniLoc	**Aesculap CranioFIX (K972332)**	**Walter Lorenz RapidFlap (K991029)**	**MacroPore Protective Sheet (Protego System) (K972913)**	**Codman Ethisorb Dura Patch (K991413)**	**Neuroregen Neurotube (K983007)**
Intended Use	MacroPoreNS CraniLoc is indicated for the fixation of bone flaps after a craniotomy.	Aesculap's CranioFIX Ttanium Clamp System is intended for use in refixation of cranial bone flaps after craniotomy.	RapidFlap is indicated for the re-attachment of the bone flap after a craniotomy.	MacroPore Protective Sheet is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton: 1. Comminuted fractures of the naso-ethmoidal and infraorbital areas 2. Comminuted fractures of the frontal sinus wall 3. Trauma of the midface or craniofacial skeleton 4. Reconstructive procedures of the midface or craniofacial skeleton. The system is not intended for use in the mandible and/or for full load bearing procedures.	The Codman Ethisorb Dura Patch is an absorbable, synthetic implant for bridging defects of the dura mater.	The Neurotube is intended for single use in patients with an injury to a peripheral nerve, in which the nerve gap is more than or equal to 8mm but less than or equal to 3cm. The nerve gap may be created primarily at the time of injury or created secondarily at the time of exploration of failed primary repair.
Design	Two disks that are attached through a threaded stem	Two disks that are attached through a threaded stem	Two disks that are attached through a threaded stem	Plates, screws, protective sheet mesh, and tacks of various shapes and sizes.	Sheet	2.3mm x 4cm long Tube
Material	Poly (L-lactide-co-D,L-lactide) 70:30, amorphous	Titanium	Titanium	Poly (L-lactide-co-D,L-lactide) 70:30, amorphous	Polyglactin 910 (90% polyglycolide, 10% L-lactide) and polydioxanone.	Polyglycolic acid (PGA)
Product Code	GXN	GXN	GXN	HRS and HWC	GXQ	JXI

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2001

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
MacroPore, Inc.
6740 Top Gun Street
San Diego, California 92121

Re: K002334
Trade/Device Name: MacroPoreNS CraniLoc
Regulation Number: 882.5250 and 882.5360
Regulatory Class: II
Product Code: GXR and HBW
Dated: January 31,2001
Received: February 1,2001

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: **MacroPore*NS* CraniLoc** K002334

Indications for Use:

MacroPore*NS* CraniLoc is indicated for the fixation of bone flaps after a craniotomy.

NRO for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002334

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____